

Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Lot 1301-1303 T₄; Lot 1411-1413 TSH; Lot 1351-1353 17-OHP – July 14, 2014

T₄, TSH and 17-OHP METHOD: FIA

ENRICHMENT LEVELS (endogenous levels not included)

<i>Analyte</i>	<i>Lot</i>	<i>Low</i>	<i>Lot</i>	<i>Intermediate</i>	<i>Lot</i>	<i>High</i>
Thyroxine (T ₄ µg/dL serum)	1301	2	1302	7	1303	11
Thyroid-Stimulating Hormone (TSH µIU/mL serum)	1411	25	1412	40	1413	80
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)	1351	25	1352	50	1353	100

ANALYTICAL INFORMATION

<i>Analyte</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>
T ₄	1301	$\bar{x} = 1.6$ CL = 0.9-2.2	1302	$\bar{x} = 6.1$ CL = 5.1-7.1	1303	$\bar{x} = 9.5$ CL = 7.2-11.8
TSH	1411	$\bar{x} = 25.3$ CL = 21.7 – 29.0	1412	$\bar{x} = 42.4$ CL = 36.1 – 48.7	1413	$\bar{x} = 86.3$ CL = 74.6 – 97.9
17-OHP	1351	$\bar{x} = 21.1$ CL = 16.4 – 25.8	1352	$\bar{x} = 44.6$ CL = 36.3 – 53.0	1353	$\bar{x} = 87.9$ CL = 69.4 – 106.4

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 20 successive, independent measurements.

Reference: Slazyk WE, Hannon WH. *Quality Assurance in the newborn screening laboratory.* In: Therrell BL Jr, editor. *Laboratory methods for neonatal screening.* Washington (DC): American Public Health Association, 1993:23-46.

Newborn Screening Quality Assurance Program

Hormones Quality Control Specimen Certification

Lot 1311-1313 TSH – July 14, 2014

Previous Lot Transition Materials (parallel testing)

T4, TSH and 17-OHP METHOD: FIA

ENRICHMENT LEVELS (endogenous levels not included)

<i>Analyte</i>	<i>Lot</i>	<i>Low</i>	<i>Lot</i>	<i>Intermediate</i>	<i>Lot</i>	<i>High</i>
Thyroxine (T ₄ µg/dL serum)						
Thyroid-Stimulating Hormone (TSH µIU/mL serum)	1311	25	1312	40	1313	80
17 α-Hydroxyprogesterone (17-OHP ng/mL serum)						

ANALYTICAL INFORMATION

<i>Analyte</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>	<i>Lot</i>	<i>Mean/ 95% CL</i>
T ₄						
TSH	1311	$\bar{x} = 22.8$ CL = 17.8 - 27.7	1312	$\bar{x} = 36.9$ CL = 28.5 - 45.4	1313	$\bar{x} = 77.5$ CL = 62.0 - 93.0
17-OHP						

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 20 successive, independent measurements.

Reference: Slazyk WE, Hannon WH. *Quality Assurance in the newborn screening laboratory*. In: Therrell BL Jr, editor. *Laboratory methods for neonatal screening*. Washington (DC): American Public Health Association, 1993:23-46.